

New super refined polysorbates

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Today, pharmaceutical manufacturers are working with new APIs that are much more effective in formulations, but increasingly prone to stability issues and more sensitive to impurities. As a result, they are looking to their suppliers to find ways to reduce impurities and enhance API efficacy, and in response, Avantor Performance Materials has introduced new versions of polysorbate products, created with an advanced process to reduce impurities down to levels not previously achieved with traditionally produced polysorbates.

Generally speaking, biopharmaceutical formulators turn to polysorbates for the benefits they provide in parenteral dosage applications (injectable, intravenous, subcutaneous), although these excipients are also used in solid and liquid dosage form products for their positive contribution to stability and API effectiveness. Composed of fatty acid esters of polyoxyethylene sorbitan, polysorbates are surfactants which are amphiphilic and non-ionic. The surface activity of polysorbates serves to stabilize proteins, by reducing the alteration or aggregation of proteins during manufacturing, distribution and storage.

When formulated with poorly soluble drugs, polysorbates provide improvements in solubilization, and emulsions with polysorbates are widely recognized among formulators for enhanced stability. Avantor's high-purity JT Baker brand polysorbate 20 and polysorbate 80 products have been used to address these issues, amid the variety of formulations and the growing presence of potentially sensitive APIs, for several years.

Super refined is a process from Croda implemented by Avantor, and the new super refined versions of polysorbate 20 and polysorbate 80 take this pursuit of greater formulation purity a step further. High-purity grade polysorbates already offer low levels of impurities to ensure high performance in formulations, but a proprietary flash chromatographic process used in making the super refined versions has been shown to remove even more polar and oxidative impurities, such as peroxides

and aldehydes. The decreased level of these impurities helps maintain API integrity and stability in formulations like parenteral drugs involving monoclonal antibodies or recombinant proteins (such as certain cancer drugs), and other formulations in suspension or emulsion dosage form.

Super refined polysorbate products make it possible for customers to match the right level of purity to their specific API needs. This is especially relevant, for example, to makers of parenteral formulations and those involved in the growing biosimilars market in regions like Asia and India.

Quality assurance is key

As the need to reduce impurities in formulations continues to influence production decisions by manufacturers, quality assurance from suppliers becomes even more critical. Suppliers must be able to match their customers' emphasis on purity with an equal commitment to the quality of materials that they provide. Customers increasingly are choosing suppliers who can offer features like cGMP manufacturing and subdivision capabilities, FDA-inspected and ISO-certified facilities, nitrogen blanket packaging and rigorous multi-compendial requirements.

For example, Avantor's JT Baker brand polysorbate products meet the requirements of the National Formulary (NF), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP) or Japanese Pharmaceutical Excipients (JPE). It's vegetable-based composition serves to reduce endotoxins, peroxides and other impurities, which in turn improves oxidative stability and shelf life. And customers are able to choose among multiple packaging sizes to match the amount of polysorbate product they buy to their manufacturing processes more closely.

Increasingly, customers are looking to work with companies who see themselves more as partners than just suppliers. The foundation of that type of relationship is confidence in the quality of the products that they purchase and we provide.